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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,931	10/05/2005	Zhiguo Su	37137-224348	6508
<div>26694 7590 07/19/2007</div> <div>VENABLE LLP</div> <div>P.O. BOX 34385</div> <div>WASHINGTON, DC 20043-9998</div>				
<div>EXAMINER</div> <div>MONSHIPOURI, MARYAM</div>				
<div>ART UNIT</div> <div>PAPER NUMBER</div> <div>1656</div>				
<div>MAIL DATE</div> <div>DELIVERY MODE</div> <div>07/19/2007</div> <div>PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,931	Applicant(s) SU ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>filed 10/10/05</u> | 6) <input type="checkbox"/> Other: ____ |

Applicant's response to restriction requirement filed 6/14/2007 is acknowledged. Applicant elected Group (a), Claims 1-3, 6-13, conjugates of 1-3 Hb and 1-3 human serum albumins without traverse. Claims 4-5 remain withdrawn as drawn to non-elected invention.

With respect to species election, applicant elected the following: purification comprising anion exchange chromatography, two step coupling.

In response to applicant's traversal arguments of the species election, restriction directed to species recited in claims 9-10 is hereby withdrawn.

DETAILED ACTION

Claims 1-3 and 6-13 are under examination on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (Biotechnology Letters, 24, 275-278, 2002, cited in the IDS) in view of Bonhard et al. (U.S. patent No. 4,336,248, issued 6/1982), further in view of known hemoglobin (protein) purification methods. Hu teaches a protein conjugate of bovine serum albumin (BSA) and bovine hemoglobin (bHb), (see Figure 1) having a molecular weight of 127 KD, wherein the ratio of bHb/BSA is 1-2 (see table 1), obtained by intramolecular two-step crosslinking method. Said conjugate was purified by gel filtration

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chromatography and was recommended and suggested to be used as blood substitutes by Hu et al. However, Hu et al. do not make or use an albumin/hemoglobin conjugate of human origin.

Bonhard, in Examples 6, 7, 11-12, teaches about conjugates of human serum proteins (including HSA) and human stroma free hemoglobin (hHb), purified by gel chromatography for human blood replacement and human organ transfusion (see column 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the conjugate of Hu and replace the bovine proteins with those from humans according to Bonhard, wherein said human proteins have been ultra purified according to common methods of purification in the art (i.e. such as those leading to production of stroma free hemoglobin etc., see claim 8). One of ordinary skill in the art is motivated in replacing the bovine proteins of Hu's conjugate with those of Bonhard and purify them to the maximum extent possible, because obviously such product will be more stoichiometric, having predictable oxygen carrier capacity, will be immunegically acceptable to humans and can be, for example, used in human blood transfusions etc., as blood substitutes as suggested by Bonhard.

Finally, one of ordinary skill in the art has a reasonable expectation of success in preparing and using such HSA/hHb product because the structure of bovine and human hemoglobin and albumin are very similar and one of ordinary skill at first glance, expects to use the same ratio of said bovine proteins for preparation of human HAS/hHb conjugates, rendering the invention obvious.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Maryam Monshipouri Ph.D.

Primary Examiner